K121031

JUN 2 1 2012

5. 510(k) Summary

This summary document is being prepared in accordance with section 21 CFR 807.92(c).

The submitter of the 510(k) is:

Michael Buenger
Associate Director, Regulatory Affairs
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Device Subject to this 510(k):

Trade Name:	WaveLight® FS200 Patient Interface 1505
Common Name:	Sterile Consumable (disposable)
Classification Name:	Consumable for use with a Powered Laser Surgical Instrument (per 21 CFR 878.4810)

5.1 Predicate Device

The legally marketed device to which we are claiming equivalence to is:

510(k) Number	Device
K101006	WaveLight® FS200 Patient Interface 1504 (Consumable cleared with the WaveLight® FS200 Laser System)

5.2 Device Description

The WaveLight® FS200 Patient Interface 1505 is a patient contact consumable (disposable) consisting of a Tubing System with integrated Suction Ring and an Applanation Cone. The flat bottom of the cone is used as an applanation plate for the patient's cornea.

5.3 Indications for Use

The WaveLight® FS200 Patient Interface 1505 is indicated to be used with the WaveLight® FS200 Laser System, consistent with the cleared Indications for Use for this ophthalmic surgical laser.

5.4 Statement of how the Technological Characteristics of the Device compare to those of the Predicate or legally marketed Device

The technological characteristics of the WaveLight® FS200 Patient Interface 1505 are equivalent to those of the predicate device. The WaveLight® FS200 Patient Interface 1505 and the predicate device WaveLight® FS200 Patient Interface 1504 are alternative consumables for use with the WaveLight® FS200 Laser System. They both consist of a Tubing System with integrated Suction Ring and an Applanation Cone.

The Tubing System with integrated Suction Ring used in the WaveLight® FS200 Patient Interface 1505 is identical to the one used in the predicate device. The main difference between the WaveLight® FS200 Patient Interface 1505 and the predicate device is the Applanation Cone.

The Applanation Cone of the predicate device consists of an aluminum cone with a bonded glass plate. The Applanation Cone of the WaveLight® FS200 Patient Interface 1505 is a one piece molded plastic cone.

5.5 Brief Summary of Nonclinical test and Results

5.5.1 Biocompatibility

Biocompatibility evaluations of materials coming into contact with the patient or fluid path have been performed against the applicable ISO 10993 standards, taking into account the FDA Guidance "Use of International Standard ISO-10993 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'. In addition, a laser exposure test designed in analogy to the laser treatment of intraocular lenses has been performed per the FDA Recognized Consensus Standard – "ISO 11979-5:2006: Ophthalmic Implants – Intraocular lenses – Part 5: Biocompatibility".

5.5.2 Sterility

The WaveLight® FS200 Patient Interface 1505 is provided sterile and intended for single use only. The product is EtO sterilized. The EtO sterilization cycle has been validated per the FDA Recognized Consensus Standard – "AAMI/ISO 11135: 2007: Medical devices – Validation and Routine Control of Ethylene Oxide Sterilization". The sterilization process for the WaveLight® FS200 Patient Interface 1505 has been validated to achieve a 10^{-6} SAL (sterility assurance level).

5.5.3 Packaging and shelf-life

Packaging and shelf-life have been validated according to the FDA Recognized Consensus Standard " ISO 11607-1: 2006: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems."

5.5.4 Function and Performance

Functional tests test were performed after sterilization, transportation and aging (real-time and accelerated).

Performance tests according to the FDA Guidance for Industry and FDA staff "Keratome and Replacement Keratome Blades Premarket Notification [510(k)] Submissions", were conducted for direct comparison of the cutting results with the predicate device. These Flap cutting tests demonstrate that the performance of the WaveLight® FS200 Patient Interface 1505 is equivalent to the one of the predicate device.

5.5.5 System validation

The WaveLight® FS200 Patient Interface 1505 has been developed and will be manufactured in compliance with section 21 CFR 820 and ISO 14971: 2007: "Medical devices - Application of risk management to medical devices". Accordingly, the use of the WaveLight® FS200 Patient Interface 1505 with the WaveLight® FS200 Laser system has been validated at the system level.

5.6 Conclusion

Non-clinical testing noted above has demonstrated that the technological characteristics affecting clinical performance of the WaveLight® FS200 Patient Interface 1505 are equivalent to those of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 21 2012

Alcon Research, Ltd.
c/o Mr. Michael Buenger
Associate Director, Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134

Re: K121031
Trade/Device Name: WaveLight® FS200 Patient Interface 1505
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX, HNO
Dated: May 11, 2012
Received: May 14, 2012

Dear Mr. Buenger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (unknown): K121031

Device Name: WaveLight® FS200 Patient Interface 1505

Indications for Use:

The WaveLight® FS200 Patient Interface 1505 is indicated to be used with the WaveLight® FS200 Laser System, consistent with the cleared Indications for Use for this ophthalmic surgical laser.

Prescription Use ___X___ AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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